

**DETAILED ACTION**

1. In view of the Appeal Brief filed on October 14, 2009, PROSECUTION IS  
HEREBY REOPENED. New grounds of set forth below.

To avoid abandonment of the application, appellant must exercise one of the  
following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply  
under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed  
by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and  
appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth  
in 37 CFR 41.20 have been increased since they were previously paid, then appellant  
must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by  
signing below:

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733

2. This is Office action is based on the 10,597,502 application filed on July 27,  
2006, which is a 371 of PCT/CH04/00067 filed February 6, 2004.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all  
obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. **Claims 1** is rejected under 35 U.S.C. 103(a) as being unpatentable over Scales US 4,405,249 in view of Felt US 5,556,429.

Scales discloses an injection device especially for bone cement, comprising:

A) a syringe body with a longitudinal axis, a front end, a connecting piece (#36), disposed at the front end and having a coaxial borehole, and a coaxial cavity (as seen in Fig below);

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B) an injection piston, which can be shifted coaxially in the cavity (as seen in Fig below);

C) a cannula, which can be connected with the connecting piece, with a central borehole and rear end (as seen in Fig below and Col 4 lines 1-5); wherein

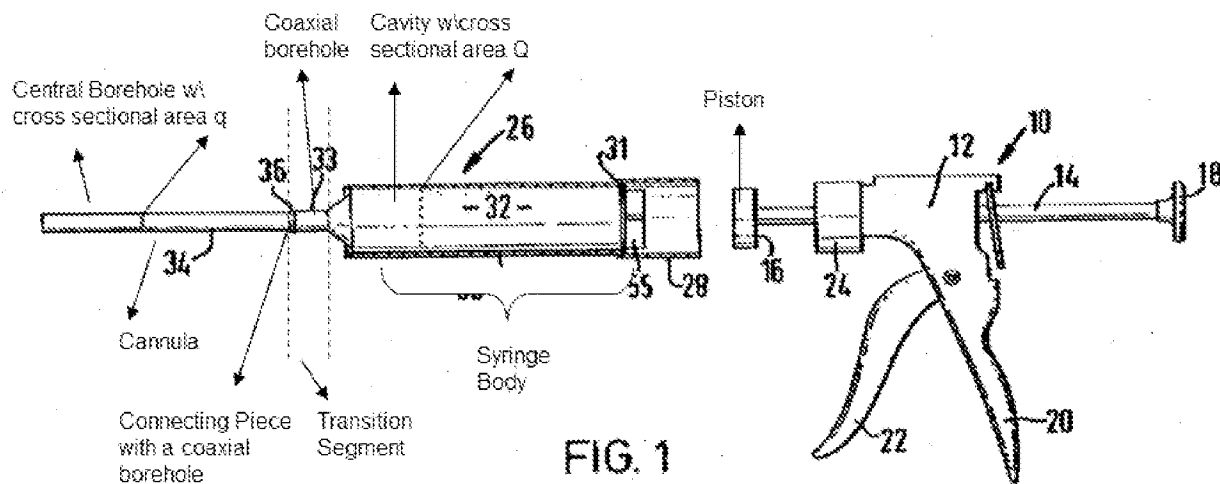
D) the front end of the syringe body has a transition segment with a coaxial borehole with constant diameter, connecting the cavity with the borehole in the connecting piece (as seen in Fig below, where the transition segment #36, as indicated between the two dashed lines has a borehole with a constant diameter); and wherein

E) the borehole in the transition segment and the central borehole have the same cross-sectional area orthogonal to the longitudinal axis at least at the rear end of the cannula (as seen in Fig below);

F) the central borehole of the cannula has a constant cross-sectional area  $q$  in the axial direction (as seen in Figs below and see also Fig 4, where the transitional segment has a borehole with a constant diameter that is the same as the bore hole of the connecting piece).

G) the cavity has a cross sectional area  $Q$  which is orthogonal to the longitudinal axis (as seen in Fig below).

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Scales discloses the cross sectional Q having a diameter of 4 cms or 40mm (see col 4 lines 35-36), but does not disclose the ratio of  $q:Q$  is 0.200 and 0.033.

However, Felt teaches that curable biomaterial have a viscosity and generally flow out of a cannula onto the surgical site, wherein the diameter of the cannula is in the order between 2-6 mm (see Col 3 lines 35-40).

It would have been obvious to one having ordinary skill in the art at the invention was made to modify the diameter of the cannula of Scales to be 2-6mm in view of Felt because these dimensions are known in the art to allow curable viscous material to flow into surgical sites, wherein the ratio of  $q:Q$  would be between 0.200 and 0.033.

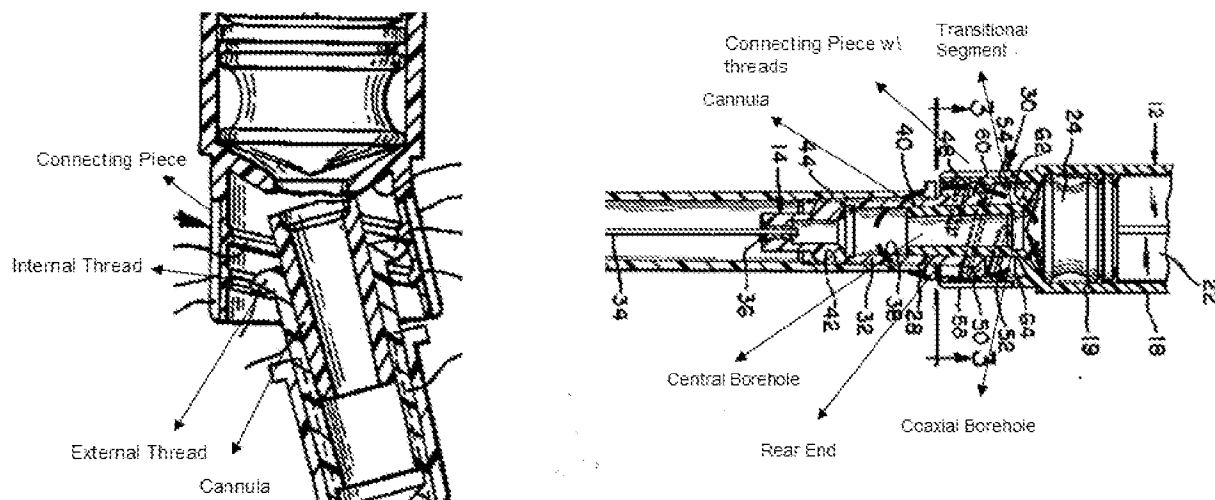
7. **Claims 5-7, 9-10, 13-16** is rejected under 35 U.S.C. 103(a) as being unpatentable over Scales US 4,405,249 and Felt US 5,556,429, as applied to claim 1 above, and in further view of Whitney US 4,220,151.

The combination of Scales and Felt discloses the claimed invention as discussed above wherein the cannula and connecting piece can be connecting by other means

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(see Col 4 lines 1-5) but does not specifically disclose the connecting piece has an internal thread, the cannula has an external thread to screw into the internal thread, which correspond to a Luer Lock connection.

However, Whitney discloses a very similar device where a cannula (#28) has an external thread (#46) to mate with an internal thread (#52) of the connecting piece, wherein a transition segment and the cannula have the same cross sectional area (as seen in Fig below), where the threads correspond to a Luer lock which allows for a fluid tight coupling between the cannula and the connecting piece (see abstract, Col 3 lines 55-61).



It would have been obvious to one having ordinary skill in the art at the invention was made to modify the combination of Scales and Felt to include the Luer lock in view of Whitney because it allows for a fluid tight coupling.

### ***Response to Arguments***

8. Applicant's arguments with respect to claims above have been considered but are moot in view of the new ground(s) of rejection. The examiner notes that the

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applicant argues that Whitney does not disclose an external thread which the examiner does not agree. Even though Whitney calls piece #48 an ear, it can be considered AN external thread that is threaded/rotated onto internal thread #52. Ears #48, #58 protrude outward from the cannula and is threaded/rotated onto thread #52 and functions as a thread (as seen in Fig 2, 4 and Col 3 lines 55-65). The applicant has not claimed an external thread spiraling along the length of the cannula, which the examiner believes the applicant is trying to convey.

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure, see PTO-892 for art cited of interest. With regards to the diameter of the cannula, the examiner would also like to point out Brown Col 3 lines 45-54, Bernard paragraph 93, Crooker paragraph 2, as well as the applicants own Background of the prior art, which teaches it is known in the art to select a cannula or tube to be sufficiently small in diameter in order to dispense a material therethrough, where one of ordinary skill would recognize proper diameter size ratios to achieve a certain flow of material out of an injection device, depending on the type of material, viscosity etc. The applicant is welcomed to contact the examiner to discuss any outstanding issues.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jan Christopher Merene/  
Examiner, Art Unit 3733

/Eduardo C. Robert/  
Supervisory Patent Examiner, Art Unit 3733